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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/630,340	07/31/2000	Victor Pan	LIFE-009	5593

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EXAMINER

CROSS, LATOYA I

ART UNIT PAPER NUMBER

1743

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/630,340

Applicant(s)

PAN ET AL.

Examiner

LaToya I. Cross

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action follows the Notice of Withdrawal from Issue dated March 16, 2005. Prosecution of the instant application has been reopened after reconsideration of the papers submitted by Applicants on October 12, 2004.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 11, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shartle '660.

Shartle '660 discloses an automated meter useful in testing for the presence of a sufficient amount of sample on a test strip. The meter comprises a means for obtaining reflectance data via a LED illumination source 42a (visible light source) and a detector 42b. The light source illuminates the sample port 12. The detector measures reflected light. A signal is provided denoting the presence of the sample. This signal causes an actuator 48 to release bladder member 14 and move sample further down the test strip. See col. 6, line 54 – col. 7, line 33. In figure 4, the automatic meter is shown as it acts on a test strip 10.

Shartle fails to explicitly teach that the reflected light is detected prior to the test strip entering into the meter. However, Shartle teaches that when sample is introduced at the sample application area, a reduction in the reflected light to the detector occurs, thereby triggering the release of the bladder. Thus, the detector, which collects the reflected light data, detects reflected light prior to sample being present at the sample application zone and when sample is present. The detector would not sense a reduction in reflected light if the detector did not detect reflected light prior to sample being present. Further, it would have been obvious to one of ordinary skill in the art that the reflected light is also detected prior to the test strip being inserted into the meter. At col. 6, lines 54-62, Shartle discloses that the user turns the meter on, thereby energizing the strip detector and sample detector. The reference further states that the strip is inserted and the presence of the strip blocks the illumination by LED 40a of detector 40b. Thus, it would have been obvious that the reflected light changes once the strip is inserted into the meter and a change in the reflected light would denote that the data is being collected prior to the strip being inserted and after the strip is inserted.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Shartle '660.

3. Claims 13 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shartle '660 in view of US Patent 5,674,699 to Saunders et al.

Shartle '660 is described in detail above. Further, the reference fails to teach the claimed wavelength to use in irradiating the test strip.

Saunders et al '699 teaches that chemicals/compounds specifically absorb light at certain wavelengths. Saunders et al '699 further teaches that the absorbances of many chemicals/compounds are known and that one of ordinary skill in the art can readily determine the wavelength at which a particular assay should be conducted to obtain maximum results. See col. 13, lines 1-29. Thus, it would have been obvious to one of ordinary skill in the art to use a wavelength suitable for reflecting light from the particular sample being deposited on the test strip in conducting the method of Shartle '660.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Shartle '660.

Response to Amendment

3. The declaration filed on October 12, 2004 under 37 CFR 1.131 has been considered but is ineffective to overcome the obviousness rejection over the Shartle reference and the obviousness rejection over Shartle in view of Saunders et al.

4. The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Shartle reference. Applicants submitted a copy of an Invention Disclosure, given to LifeScan as an attempt to antedate the Shartle reference. The Invention Disclosure was said to have been dated prior to July 20, 1998, which is the effective filing date of Shartle. Upon further review of the Invention Disclosure, the Examiner has found the disclosure to be insufficient to prove reduction to practice, prior to the effective date of the Shartle reference. Specifically, the disclosure does not show the invention as described in the instant claims. The figures provided on pages 5 and 6 of the Invention Disclosure show only a portion of the claimed device. The claimed device comprises three components – means for collecting reflectance data, means for comparing reflectance data and means for actuating fluid sample movement. The device shown in the Invention Disclosure (figures on pages 5-6) shows only the means for collecting reflectance data (light source and light detector) and the means for comparing reflectance data (output signal). The Invention Disclosure does NOT show

the means for actuating fluid sample movement as recited in both independent claims 11 and 15.

MPEP §§715.01 and 715.02 provide the guidelines for overcoming prior art using declarations under 37 CFR 1.131. The manual states that the declaration “must establish possession of either the whole invention claimed or something falling within the claim (such as a species of a claimed genus)”. Since Applicants’ declaration failed to provide a showing for the means for actuating fluid sample movement, as recited in the claims, the declaration is insufficient to antedate the Shartle reference.


Thus, the obviousness rejections over Shartle and Shartle in view of Saunders et al are hereby reinstated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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